



Distal stent graft–induced new entry after TEVAR or FET: insights into a new disease from EuREC

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Abstract: Background: The study sought to learn about incidence and reasons for distal stent graft-induced new entry (dSINE) after thoracic endovascular aortic repair (TEVAR) or after frozen elephant trunk (FET) implantation, and develop prevention algorithms. Methods: In an analysis of an international multicenter registry (EuREC [European Registry of Endovascular Aortic Repair Complications] registry), we found 69 dSINE patients of 1430 (4.8%) TEVAR patients with type B aortic dissection and 6 dSINE patients of 100 (6%) patients after the FET procedure for aortic dissection with secondary morphological comparison. Results: The underlying aortic pathology was acute type B aortic dissection in 33 (44%) patients, subacute or chronic type B aortic dissection in 34 (45%) patients, acute type A aortic dissection in 3 patients and remaining dissection after type A repair in 3 (8%) patients, and acute type B intramural hematoma in 2 (3%) patients. dSINE occurred in 4.4% of patients in the acute setting and in 4.9% of patients in the subacute or chronic setting after TEVAR. After the FET procedure, dSINE occurred in 5.3% of patients in the acute setting and in 6.5% of patients in the chronic setting. The interval between TEVAR or FET and the diagnosis of dSINE was 489 ± 681 days. Follow-up after dSINE was 1340 ± 1151 days, and 4 (5%) patients developed recurrence of dSINE. Morphological analysis between patients after TEVAR with and without dSINE showed a smaller true lumen diameter, a more accentuated oval true lumen morphology, and a higher degree of stent graft oversizing in patients who developed dSINE. Conclusions: dSINE after TEVAR or FET is not rare and occurs with similar incidence after acute and chronic aortic dissection (early and late). Avoiding oversizing in the acute and chronic settings as well as carefully selecting patients for TEVAR in postdissection aneurysmal formation will aid in reducing the incidence of dSINE to a minimum.

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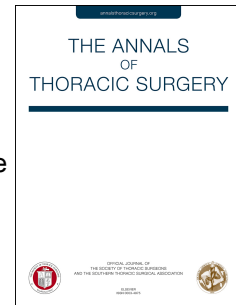
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Running head: dSINE after TEVAR/ FET

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Abstract

Background. To learn upon incidence and reasons for distal stent-graft induced new entry (dSINE) after thoracic endovascular aortic repair (TEVAR) or after frozen elephant trunk (FET) implantation, and to develop prevention algorithms.

Methods. Analysis of an international multi-center registry (European Registry of Endovascular Aortic Repair Complications- EuREC), 69 dSINE patients out of 1430 TEVAR patients for type B aortic dissection (4,8 %) and 6 dSINE patients out of 100 patients after the FET procedure for aortic dissection (6 %) with secondary morphological comparison.

Results. The underlying aortic pathology was acute type B aortic dissection in 33 patients (44%), subacute and/ or chronic type B aortic dissection in 34 patients (45%), acute type A aortic dissection in 3 patients and remaining dissection after type A repair in 3 patients (8%), acute type B intramural hematoma in 2 patients (3%). dSINE occurred in 4.4% of patients in the acute setting and in 4.9% of patients in the subacute/ chronic setting after TEVAR . After, the FET procedure, dSINE occurred in 5.3% of patients in the acute setting and in 6.5% of patients in the chronic setting. The interval between TEVAR/ FET and the diagnosis of dSINE was 489 ± 681 days. Follow-up after dSINE was 1340 ± 1151 days, 4 patients developed recurrence of dSINE (5%). Morphological analysis between patients after TEVAR with and without dSINE showed a smaller true lumen (TL) diameter, a more accentuated oval TL morphology and a higher degree of stent-graft oversizing in patients who have developed dSINE.

Conclusions. dSINE after TEVAR/ FET is not rare and occurs with similar incidence after acute and chronic aortic dissection- early and late. Avoiding oversizing in the acute and in the chronic setting as well as carefully selecting patients for TEVAR in post-dissection aneurysmal formation will aid in reducing the incidence of dSINE to a minimum.

Keywords: TEVAR, distal stent-graft induced new entry, complications, treatment

Thoracic endovascular aortic repair (TEVAR) since its introduction in the late 90ies, has become the standard treatment for various thoracic aortic pathology in particular in patients with acute complicated type B aortic dissection (1-5). However, as with each and every new treatment modality, limitations and complications become apparent. One of them when choosing the TEVAR/ FET approach was stent-graft induced new entry (SINE) either proximal (often leading to retrograde type A aortic dissection) or distal (dSINE- usually leading to antegrade false lumen reperfusion) (6-10). Knowledge regarding dSINE developed gradually Japanese and Chinese series pioneered knowledge and a recent review summarized the currently known key components (11-13). However, no multicenter effort pooling a large cohort of patients is available.

The aim of this study was to learn upon incidence and reasons for dSINE after TEVAR or FET and to develop prevention algorithms to reduce the remaining risk of occurrence to a minimum.

Patients and Methods

Patients. Analysis of an international multi-center registry (European Registry of Endovascular Aortic Repair Complications- EuREC from November 1999 to March 2017), 69 dSINE patients out of 1430 TEVAR patients for type B aortic dissection (4,8 %) and 6 dSINE patients out of 100 patients after the FET procedure for aortic dissection (6 %). Secondary morphological comparison of the acute type B subgroup having developed dSINE with patients after TEVAR for acute type B aortic dissection without development of dSINE.

Definition of dSINE, definition of true lumen shape (definition of ovality) and levels of measurement and evaluation of aortic TL and FL diameter and thrombosis status. dSINE was defined as any newly detected communication between lumina at the distal end of the

stent-graft having been absent either during primary implantation or during completion imaging at follow-up. Oval true lumen shape was defined as difference between the long and the short axis diameter at the distal end of the stent-graft as shown in **Figure 1**. The long axis length was used to predict the pre-dissection aortic diameter in patients with acute dissection. In these patients, stent-graft diameter was chosen according to predicted pre-dissection aortic diameter with 0% oversizing. In case of chronic aortic dissection the average true lumen diameter (according to long and short axis) was used and about 10% oversizing was applied in the first author's center.

Parameters. We collected clinical data, including any kind of previous aortic surgery or intervention, underlying aortic pathology and extension of aortic disease. Procedural data included the index TEVAR procedure, elective or emergent intervention, number of prostheses, covered length and landing zones according to current definitions. The false lumen thrombosis status at different levels was recorded as was the timepoint of occurrence of dSINE. We collected treatment strategies applied and finally compared aortic diameters and aortic shape in patients having had TEVAR for acute type B aortic dissection developing dSINE with aortic diameters and aortic shape in a control group of patients having had TEVAR for acute type B aortic dissection not developing dSINE. We did not collect data regarding side-branch stenting during the index procedure. Information on clinical outcome after distal TEVAR extension or after open surgery was not collected.

Statistical analysis. All values are shown as number (percentage) or as mean \pm standard deviation. IBM SPSS Statistics 24 for Macintosh (Armonk; NY) was used for statistical analysis. The University Heart Centre Freiburg's acute type B aortic dissections database served to compare the aortic as well as the stent-graft diameters. The Mann-Whitney U test was used to compare continuous variables between both groups.

Results

Patient demographics. Patient demographics are shown in **Table 1**. Mean age was 58 ± 13 years and 24% had any kind previous aortic operation or intervention.

Aortic characteristics. The underlying aortic pathology was acute type B aortic dissection in 33 patients (44%), subacute and/ or chronic type B aortic dissection in 34 patients (45%), acute type A aortic dissection in 3 patients and remaining dissection after type A repair in 3 patients (8%), acute type B intramural hematoma in 2 patients (3%). In patients with chronic type B aortic dissection, the interval between the acute event and TEVAR was 472 ± 715 days. The presumed etiology as well as the extent of the dissective process are shown in **Table 2**. The main indications for TEVAR were malperfusion and (contained) rupture in the acute phase and diameter increase in the subacute and chronic phase.

Procedural characteristics- index procedure. Forty-six procedures were performed electively whereas 36% were performed under emergency conditions. Procedural details are shown in **Table 3**. **Table 4** shows the thrombosis status of the false lumen at different levels after the index procedure. Fifteen patients received tapered stent-grafts whereas 8 had a primary tapered prosthesis and another 7 had a tapered stent-graft as the most distal prosthesis. One patient received a bare stent distal extension during the index procedure.

dSINE incidence and time interval to index procedure. dSINE was observed in 69 out of 1430 patients after TEVAR (4,8 %) and in 6 out of 100 patients after the FET procedure (6 %). dSINE occurred in 4.4% of patients in the acute setting (33 out of 739 patients) and in 4.9% of patients in the subacute/ chronic setting after TEVAR (34 out of 691 patients). After the FET procedure, dSINE occurred in 5.3% in the acute setting (3 out of 54 patients) and in

6.5% in the chronic setting (3 out of 46 patients). The interval between TEVAR/ FET and the diagnosis of dSINE was 489 ± 681 days.

dSINE management. In 28 patients (37%) a conservative approach was chosen, 42 patients (56%) underwent TEVAR extension and 5 patients (7%) underwent open surgical conversion. Follow-up after dSINE was 1340 ± 1151 days, 4 patients developed recurrence of dSINE (5%) (**Table 5**). **Figure 2** shows CTA scans of a patient with the recurrent occurrence of dSINE.

Aortic diameters in patients with and without dSINE. Morphological analysis between patients after TEVAR with and without dSINE showed a smaller TL diameter (23 ± 7 vs. 34 ± 6 , $p < 0.001$), a more accentuated oval postoperative stent-graft morphology (5 ± 4 (ratio 1:1.18) vs. 2 ± 2 (ratio 1:1.08), $p < 0.001$) and a higher degree of stent-graft oversizing in patients having developed dSINE (10 ± 6 vs. 3 ± 6 , $p < 0.001$) (**Table 6**). The entire measurements in several aortic segments are summarized in Supplemental Table 1.

Comment

The majority of patients had acute type B aortic dissection as the underlying aortic pathology warranting TEVAR, followed by a high number of patients undergoing TEVAR for subacute and chronic type B aortic dissection. Where type B aortic dissection has been regarded as the hazard-free dissection without the need for treatment in many cases, recent knowledge upon risk factors for the presence or the development of early or late complications has completely turned the page (**4,15-17**). This has led to a broader application of TEVAR in this patient cohort which per se also leads to a potentially higher number of patients sustaining early or late complications such as dSINE.

Also in patients with post-dissection aneurysmal formation, TEVAR has gained widespread acceptance but it has to be taken into the consideration that TEVAR alone is rarely capable to effectively treat the complex underlying pathology where the efficacy is strongly dependent on various conditions (18). As to the nature of the disease, the membrane has often stiffened over time and the potential for remodeling is lower. Therefore, the shear-stress between the distal end of the stent-graft and the dissection membrane is high and may cause dSINE- early or late- tapered stent-graft seem to play a major role in reducing dSINE to a minimum in these clinical scenarios. Despite FET and TEVAR being different conceptual approaches, the pathophysiological mechanisms behind the occurrence of dSINE are very similar.

Results after surgery for acute type A aortic dissection have made a leap towards lower mortality in the last two decades and the FET technique is applied more frequently (19-21). As many patients will undergo a stringent follow-up in an aortic outpatient clinic, aneurysm formation in residual dissection after type A repair is frequently seen. (22,23). The FET technique is applied in patients with acute type A aortic dissection, mainly in those where the primary entry tear cannot be excluded by surgical means due to its distal location (24,25). Similar to classical TEVAR, the interaction between the distal end of the stent-graft and the dissection membrane may lead to dSINE due to the before mentioned mechanism with the addition that the stent-graft design of the FET prosthesis might also play an important role with regard to distribution of radial force (26).

With regard to procedural characteristics, there was an even distribution between acute and chronic indications for both TEVAR and FET. Manufacturer, size as well as number of prostheses were evenly distributed and in the majority of patients.

The incidence of dSINE was similar between the acute and the chronic setting after both- TEVAR and the FET procedure indicating mechanisms of occurrence beyond the timepoint of treatment. The high mean variation when dSINE occurred- early or late after the index procedure- shows the unpredictability. Interestingly, dSINE frequently was a diagnosis by chance during follow-up and was rarely associated with acute chest pain which is frequently seen in acute aortic dissection irrespective of type. Treatment approaches varied substantially from conservative therapy to thoracoabdominal replacement (27). As these are registry data and imaging was not available, the reasons why one or the other treatment modality was chosen, remain speculative.

As a classical control group is lacking, we aimed at understanding similarities and differences between patients with and without developing dSINE. Consequently, we selected the subgroup of patients who underwent TEVAR for acute type B aortic dissection and compared aortic diameter and shape at the level of the distal end of the stent-graft with patients who underwent TEVAR for acute type B aortic dissection in the first author's institution who did not develop dSINE. Patients developing dSINE had both- a smaller true lumen diameter and a more oval true lumen shape indicating true lumen compression and eventually malperfusion during the initial phase and eventually most important, that oversizing of the stent-grafts used was more frequent in the ones who developed dSINE underlining the importance of sizing. Recent evidence suggested that dSINE occurs more frequently in the hyperacute stage which prompted many to delay therapy if the clinical course permits to do so. When we set up this study, we did not differentiate into hyperacute and acute which does not let us to distinguish between these two phases.

Rationale for aggressive treatment- From a functional point of view in primary type B aortic dissection, we do have data to correlate the size of the primary entry tear to progression of

disease in particular with regard to diameter progression. This mirrors exactly what we do observe in dSINE- rapid diameter increase in the majority of cases. This is what drives the attitude to follow an aggressive treatment strategy.

Stent-graft sizing in patients with acute type B aortic dissection is demanding and several options are available. Most importantly, one has to understand that during the acute event, there is an acute diameter increase in particular in the proximal descending aorta by 20%, this has been shown by retrospective imaging studies (28). However, the proximal landing zone remains the most important determinant when choosing the appropriate stent-graft size- tapered devices present a very good solution in combining both- needs and demands- regarding the correct stent-graft size.

Recently, new approaches like the PETTICOAT or the STABILIZE concept have entered the clinical arena and it remains to be shown if their routine use will be able to further reduce the occurrence of dSINE (29,30). Additionally, a “distal first” concept of deployment in case of at least 2 prostheses has been advocated to prevent dSINE which also remains to be confirmed by larger studies (13).

Limitations and strengths. This analysis has all limitations associated with retrospectively collected registry data. Potential coding errors, absence of external validation and interobserver variability in particular due to the lack of imaging data for detailed morphologic analyses. On the other hand, this is a respectively large series of a new disease where- to date- little has been known with regard to incidence, mechanisms behind the development and finally, where initial recommendations for prevention can be provided.

Summarizing, dSINE after TEVAR/ FET is not rare and occurs with similar incidence after acute and chronic aortic dissection- early and late. Avoiding oversizing in the acute and in the chronic setting as well as carefully selecting patients for TEVAR in post-dissection aneurysmal formation will aid in reducing the incidence of dSINE to a minimum.

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Figure legends

Figure 1. The CTA scan shows the measurement of the ovality of the stent-graft at the distal end and it's calculation.

Figure 2. (A) Postoperative computed tomography angiography (CTA) scan of a patient after total aortic arch replacement via the frozen elephant trunk technique. (B) Follow-up CTA revealed a dSINE and was treated by TEVAR (C) In the same patient a dSINE occurred once again (D) and was treated by TEVAR once more (E).

Table 1- Baseline characteristics

	n=75
Demographics	
Male	50 (67)
Age	58 ± 13
Medical history	
Hypertension	68 (91)
Coronary Artery Disease	11 (15)
Previous CABG	4 (5)
Previous aortic surgery/intervention*	18 (24)
Ascending	16 (21)
Arch	5 (7)
Descending	2 (3)
Abdominal	0 (0)

Data are presented as number (%); CABG, coronary artery bypass grafting *multiple mentions possible

Table 2- Aortic characteristics

	n=75
Underlying aortic disease	
Acute type A dissection/ remaining dissection after type A repair	6 (8)
Acute type B dissection	33 (44)
Subacute/chronic type B dissection	34 (45)
Intramural hematoma	2 (3)
Days between acute event and TEVAR in chronic type B aortic dissection	472 ± 715
Presumed etiology*	
Atherosclerotic/hypertensive	61 (81)
Degenerative	7 (9)
Connective tissue disease	5 (7)
Traumatic	2 (3)
Other	1 (1)
Extension of dissection	
→ Descending	1 (1)
→ Abdominal	23 (31)
→ Iliac arteries	49 (65)
N/A	2 (3)

Data are presented as number (%) or as mean ± standard deviation; *, multiple mentions possible; N/A, not available

Table 3- Procedure characteristics

	n=75
Type of procedure	
Elective	46 (61)
Emergency	27 (36)
N/A	2 (3)
Type of Prosthesis*	
Medtronic ©	32 (43)
Gore ©	16 (21)
Bolton Medical ©	20 (27)
Vascutek ©	6 (8)
N/A	2 (3)
Number of prostheses	
n=1	63 (84)
n=2	8 (11)
n=3	4 (5)
Landing zone	
Zone 2	47 (63)
Zone 3	27 (36)
Zone 4	1 (1)
Intended or accidental overstenting of arch vessels	35 (47)
Left subclavian artery	34 (45)
Brachiocephalic trunk	1 (1)
Supraaortic transposition*	21 (28)
Carotid-subclavian bypass	21 (28)
Extraanatomic bypass to the left subclavian artery	1 (1)
Ascendo-Bicarotical bypass	1 (1)
Distal part of the stent-graft crosses thoracoabdominal transition	9 (12)
Distal extension with bare stent	1 (1)
Covered length, mm	174 ± 51

Data are presented as number (%) or as mean ± standard deviation; mm, milimetre; *, multiple mentions possible; N/A, not available;

Table 4- Early and late postoperative aortic characteristics

	n=75
Immediate postoperative false lumen status at stent-graft level	
Thrombosed	45 (60)
Partially thrombosed	26 (35)
Patent	3 (4)
Immediate postoperative false lumen status at thoracoabdominal transition	
Thrombosed	16 (21)
Partially thrombosed	25 (33)
Patent	32 (43)
N/A	2 (3)
Occurrence of dSINE, days since TEVAR	489 ± 681
False Lumen Status at stent-graft level (at diagnosis of dSINE)	
Thrombosed	28 (37)
Partially thrombosed	36 (48)
Patent	9 (12)
N/A	2 (3)
False Lumen Status at thoracoabdominal transition (at diagnosis of dSINE)	
Thrombosed	14 (19)
Partially thrombosed	23 (31)
Patent	35 (47)
N/A	3 (4)

Data are presented as number (%) or as mean ± standard deviation; N/A, not available

Table 5- Management dSINE

	n=75
Conservative	28 (37)
TEVAR extension	42 (56)
Classical surgery	5 (7)
Follow-up after dSINE, days	1340 ± 1151
Recurrence of dSINE	4 (5)

Data are presented as number (%) or as mean ± standard deviation

Table 6- Aortic diameters

	dSINE (+)	dSINE (-)	p-value
Patients with acute type B dissection	33	71	
Mean preoperative true lumen diameter mm	23 ± 7	34 ± 6	<0.001
Covered length, mm	171 ± 42	150 ± 35	0.013
Mean stent diameter, mm	33 ± 5	37 ± 5	<0.001
Postoperative stent diameter ovality, mm	5 ± 4	2 ± 2	<0.001
Mean oversizing, mm	10 ± 6	3 ± 6	<0.001

Data are presented as number (%) or as mean ± standard deviation; N/A, not available; mm, millimeter

